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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,916	01/10/2006	Noriyuki Sato	0020-5461PUS1	5447
2292	7590	12/18/2007	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			HUFF, SHEELA JITENDRA	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1643	
NOTIFICATION DATE		DELIVERY MODE		
12/18/2007		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[mailroom@bskb.com](mailto:mailroom@bskb.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/563,916	SATO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 November 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19,22-25 and 27-30 is/are pending in the application.  
 4a) Of the above claim(s) 8-18,22-25 and 27-30 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7 and 19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/27/06;1/10/06</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-7 and 19 (species SEQ ID NO. 8) in the reply filed on 11/14/07 is acknowledged.

Art on SEQ ID NO. 8 was not found therefore the search was expanded to SEQ ID NO. 2.

Claims 1-7 and 19 (as they read on SEQ ID NO. 2 and 8) are currently under consideration.

***Information Disclosure Statement***

The IDS filed 4/27/06 and 1/10/06 have been considered and initialed copies of the PTO-1449 are enclosed.

***Claim Rejections - 35 USC § 112***

Claims 1-7 and 19 (as they read on SEQ ID NO. 2 and 8) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to peptides and pharmaceutical compositions comprising said peptides. The use for the peptides is as cancer vaccines. However, the specification has only provided in vitro data which shows the

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induction of CTL from human peripheral blood mononuclear cell in vitro. There is no in vivo data.

Thus, the specification provides no exemplification of or guidance on how to use the claimed prevention formulation. The goal of tumor vaccination is the induction of tumor immunity to prevent tumor recurrence and to eliminate residual disease, however, Essell (J. NIH Res. 1995 7:46) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly the last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p. 48, para 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work". As a venture capitalist of the director of product development at a large pharmaceutical company and you're likely to get the same response." (p. 1 para 1).

Furthermore, Boon (Adv. Can. Res. 1992 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization

and several lines of evidence suggest that large tumor burdens can tolerate or at least depress the capability to respond against the tumor (p. 206, para 2).

Furthermore, Lee et al, J. Immunology vol. 163 p. 6296 (1999) shows that peptide based vaccines "can effectively generate a quantifiable T cell -specific immune response in the PBMC of cancer patients, though such a response does not associate with a clinically evident regression of metastatic melanoma" (abstract).

Thus, in view of the contemporary knowledge in the art of the general lack of successful applications of vaccines for the prevention of human diseases as discussed above, as well as the unpredictability in the art pertaining to an immune response against in patients with large tumor burdens as discussed above, as well as the lack of sufficient guidance in the specification, one of skill in the art would be forced into undue experimentation in order to use the invention as claimed.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 7 and 19 (as they read on SEQ ID No. 2) are rejected under 35 U.S.C. 102(e) as being anticipated by Straten et al US 2007/0036811 (filed 4/11/03).

This reference discloses SEQ ID NO. 48 which is identical to applicant's SEQ ID NO. 2. The peptide is also disclosed in a pharmaceutical composition ((see [0195]+)).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Sheela J. Huff*  
Sheela J Huff  
Primary Examiner  
Art Unit 1643

sjh